In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 22-809V

MELISS LANGERT,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: June 13, 2025
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Leah V. Durant, Law Offices of Leah V. Durant, Washington, DC, for Petitioner.

Ryan D. Pyles, U.S. Department of Justice, Washington, DC, Respondent.

ENTITLEMENT DECISION[1]

On July 26, 2022, Meliss Langert filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program).[2] Petitioner alleges that she suffered Guillain-Barré syndrome ("GBS") as a result of receiving the tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine on September 4, 2019. Petition (ECF No. 1) at 1.

I determined that this matter could be fairly resolved via ruling on the record, and both sides filed briefs in support of their positions. Petitioner's Brief, filed Aug. 9, 2024 (ECF No. 41) ("Br."); Respondent's Opposition, filed Oct. 31, 2024 (ECF No. 47) ("Opp."); Petitioner's Reply, filed Jan. 13, 2025 (ECF No. 49). The matter is now ripe for resolution. For the reasons set forth

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

in more detail below, I hereby deny entitlement. Petitioner has not preponderantly established that her GBS (assuming it *could* be caused by the Tdap vaccine) began in a medically-acceptable timeframe, when measured from the date of vaccination.

I. Factual Background

Petitioner's pre-vaccination medical history includes several years of treatment for severe chronic low back pain, resulting in spinal and back procedures. Ex. 12 at 12; Ex. 7 at 21, Ex. 10 at 48–50. In fact, she previously complained of leg numbness and tingling that arguably was a product of such issues. Ex. 7 at 21. Much of this treatment, however, occurred nearly three years prior to the vaccination at issue—making it difficult to associate it with what transpired in the post-vaccination timeframe. Otherwise, the filed medical records establish persistent concerns with a likely sinus infection in the summer of 2019. Ex. 11 at 70, 72.

Vaccination and Initial Symptoms

On September 4, 2019, Ms. Langert received a Tdap vaccine during an urgent care visit following a dog bite. Ex. 1 at 1–2. The next day (September 5th), she saw an optometrist, reporting that a "few days ago [she] was on [the] phone for a few hours and awoke the next morning with OD [right eye] 'out of focus[;]' improved with lifting upper eyelid, next day both eyes were out of focus, no physical discomfort, bilateral temporal discomfort, improves with chin down." Ex. 15 at 5. She was deemed to have likely experienced sudden-onset vertical diplopia[3] of both eyes, and an MRI was proposed. *Id.* at 6.

On September 6, 2019 (now two days post-vaccination), Petitioner went to a hospital emergency department, reporting fatigue, myalgias, nausea, and dizziness with close-to-syncopal episodes "[s]ince" her vaccination two days before. Ex. 12 at 11. Notes from this visit indicate that Ms. Langert displayed "elevated sed[imentation] rate" (suggesting the presence of some degree of inflammation), and that she attributed her condition to the Tdap vaccine, but her exam revealed no obvious problems and she otherwise seemed well, so she was discharged that same day. *Id.* at 10–11.

In further follow-up to her concerns that the vaccination explained her symptoms, Petitioner visited rheumatologist Ashima Malik, M.D., on September 9, 2019, reporting "aches and pains after [T]dap injection," and in particular back pain, which she stated had begun on September 5th (or one day post-vaccination), and which she deemed to be severe. Ex. 28 at 73–74. She also was at this time experiencing leg weakness but no numbness or tingling. *Id.* at 74.

[3] "Diplopia" is defined as "the perception of two images of a single object." *Diplopia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=14354&searchterm=diplopia (last visited June 13, 2025).

A physical exam performed at this time did not reveal notable strength/weakness deficits in Petitioner's limbs, and also resulted in normal reflexes. Ex. 28 at 77. Dr. Malik speculated that Petitioner may have experienced a "severe post vaccine [side effect with] near syncope/hypertension/dehydration and severe myalgia," and proposed that Petitioner seek emergency care again if she began to experience greater weakness of respiratory symptoms, since these kinds of complications could provide evidence of "demyelinating disease and GBS like syndrome[s] that are rare but can be seen [with] inactivated vaccine[s]." *Id.* at 79. (Petitioner also around this time visited a spine and pain management treatment center she had previously utilized for prior pain concerns, reporting that she had begun experiencing lower back pain the day after vaccination (September 5, 2019) followed by lower extremity weakness, with pain radiating to her legs and feet. Ex. 10 at 16).

Emergency Treatment and Hospitalization

Petitioner returned to the emergency department on September 11, 2019, reporting "all over joint pain" and weakness after receipt of the Tdap vaccine. Ex. 12 at 68. She had difficulty moving her right leg, but could "maintain position" in bed when the leg was passively flexed, and did not display objective weakness when moved by a treater. *Id.* at 69. A lumbar MRI performed at this time revealed evidence of slipped vertebrae but was largely otherwise normal, as was a brain/ocular orbit MRI (except for some evidence of "chronic small vessel ischemic changes" and pansinusitis[4]). Ex. 17 at 9–11. Petitioner also went back to the spinal pain center the next day for evaluation of her lower back pain. Ex. 10 at 10–14. There she received a diagnostic medial branch nerve block[5] and was referred to neurology for an EMG.[6] *Id.* at 14.

Petitioner's symptoms continued to progress, however, and on September 13, 2019, she was taken to the hospital by EMS personnel. Ex. 29 at 6. The records from this emergency intervention note that Petitioner had reported post-vaccination "complications' consistent with what is discussed above, and that "this morning she began to notice weakness in her (L) leg, and now she has almost no movement in both legs," as well as more vision disturbances. *Id.*

[4] "Pansinusitis" is defined as "inflammation involving all of the paranasal sinuses on one side." *Pansinusitis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=36617&searchterm=pansinusitis (last visited June 13, 2025).

[5] "Nerve Block" is a "regional anesthesia achieved by making extraneural or paraneural injections of anesthetics next to the nerve whose conductivity is to be cut off." *Nerve Block*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=60799&searchterm=nerve+block (last visited June 13, 2025).

[6] An electromyogram ("EMG") is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any variety of surface of electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." *Electromyography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited June 13, 2025).

Petitioner was thereafter hospitalized from September 13–19, 2019. The history section from Petitioner's initial treatment records note that she began reporting limb and hip pain "[s]hortly after" her September 4th vaccination, and that her pain had resolved but she was still experiencing weakness in her legs, double vision, and finger-tip tingling. Ex. 12 at 137. Petitioner received IVIG[7] treatment during her hospitalization, which seemed to cause improvement, and she was eventually discharged to acute in-patient rehabilitation. *Id.* at 164. Upon discharge, Petitioner received a GBS diagnosis, and it was speculated that her vaccination was related. *Id.* at 162.

Petitioner remained in rehab until mid-October 2019. *Id.* at 370. During this period, she noted recurrence of double vision whenever she sat up, but was able to ambulate with a cane (for at least short distances). *Id.* She subsequently had a follow-up visit with a neurologist in November 2019, by which point she was receiving physical therapy ("PT"). Ex. 14 at 15. Petitioner now required use of a walker, and displayed right foot drop, plus more recent left side face numbness. *Id.* However, her vision symptoms were again noted as having improved, and additional MRIs did not reveal any concerning neurologic issues. Ex. 17 at 7.

Additional records filed reflecting treatment Petitioner received into 2020 do not shed much light on the likely cause of her neurologic illness. By January 2020, Petitioner was finding increased strength in the wake of continued PT, although she was still experiencing right leg weakness and some foot cramping. Ex. 14 at 32. An additional brain MRI performed in January 2020 revealed no new or concerning neurologic issues, although it was consistent with prior sinus-related findings. Ex. 17 at 5–6. Petitioner was formally discharged from PT later that summer, although she was still experiencing some balance issues plus fatigue and cramping/aching. Ex. 9 at 53–54.

By August 2020, Petitioner continued to experience right leg cramping, as well as some right-sided face numbness. Ex. 14 at 55. She was advised to start again with nerve pain medication (which she had tapered off from earlier in the year) to alleviate the symptoms. *Id.* at 56. A CT scan performed in November 2020 also confirmed the existence of chronic sinusitis which had progressed over the last several years. Ex. 17 at 3.

II. Expert Reports

A. *Petitioner's Expert — David M. Simpson, M.D.*

Dr. Simpson, a neurologist, offered three written reports in this matter. Report, dated Sept. 24, 2023, filed as Ex. 32 (ECF No. 34-1) ("Simpson First Rep."); Report, dated Mar. 29, 2024,

[7] "Intravenous Immunoglobulin" is defined as "a pooled antibody, and a biological agent used to manage various immunodeficiency states and a plethora of other conditions, including autoimmune, infectious, and inflammatory states. The ultimate goal of this therapy is to normalize a compromised immune system." *Intravenous Immunoglobulin (IVIG)*, National Library of Medicine, https://www.ncbi.nlm.nih.gov/books/NBK554446/ (last visited June 13, 2025).

filed as Ex. 48 (ECF No. 36) ("Simpson Supp. Rep.") Report, dated June 30, 2024, filed as Ex. 49 (ECF No. 40-1) ("Simpson Second Supp. Rep."). Dr. Simpson opines that Ms. Langert was properly diagnosed with GBS, and further maintains that the onset of her neurological symptoms (beginning five days post-vaccination) is consistent with the medical literature for a vaccine-induced GBS. Simpson First Rep. at 9.

Dr. Simpson is a Professor of Neurology and the Director of the Neuromuscular Division and Clinical Neurophysiology Laboratories at the Icahn School of Medicine at Mount Sinai, where he has worked as an Attending Neurologist since 1984. *See* Curriculum Vitae, filed Sept. 29, 2023 (ECF No. 34-2) ("Simpson CV") at 2. He received his medical degree from SUNY at Buffalo School of Medicine and underwent residency and fellowship training at Cornell University Medical Center and Massachusetts General Hospital. *Id.* at 1. He is certified by the National Board of Medical Examiners, the American Board of Psychiatry and Neurology with subspecialties in Clinical Neurophysiology and Neuromuscular Medicine, and the American Board of Neuromuscular and Electrodiagnostic Medicine. *Id.* Dr. Simpson has published extensively, and has given numerous presentations and lectures on the subject of neurological disorders, including peripheral neuropathy. *Id.* at 3–95.

First Report

Before addressing his medical opinion in the matter, Dr. Simpson briefly summarized the pertinent medical facts and circumstances. *See generally* Simpson First Rep. at 1–6. There are, he explained, several biologic mechanisms by which a vaccine might lead to a neurologic illness—molecular mimicry; neurotoxic effect; immune complex formation; and/or loss of self-tolerance—adding further that "ample evidence" associates vaccination and a variety of demyelinating neuropathies. *Id.* at 7; *see also* T. Safranek et al., *Reassessment of the Association between Guillain-Barré Syndrome and Receipt of Swine Influenza Vaccine in 1976-1977: Results of a Two-State Study*, 133 Am. J. Epidemiol. 940 (1991), filed as Ex. 35 (ECF No. 34-3) ("Safranek") (discussing the outbreak of GBS cases following the swine flu vaccine program in 1976); M.A. Pou et al., *Development of Autoimmune Diseases after Vaccination*, 14 J. Clin. Rheumatol. 243 (2008), filed as Ex. 37 (ECF No. 34-5) (describing two cases of giant cell arteritis and rheumatoid arthritis that appeared following receipt of influenza ("flu") and tetanus toxoid vaccines).

To connect the Tdap vaccine with GBS, Dr. Simpson referenced several somewhat-old case reports involving the tetanus toxoid vaccine. Simpson First Rep. at 7; N. Newton and A. Janati, *Guillain-Barré Syndrome after Vaccination with Purified Tetanus Toxoid*, 80 Southern Med. J. 1053, 1054 (1987), filed as Ex. 43 (ECF No. 34-12) ("Newton & Janati") (finding receipt of tetanus toxoid-containing vaccine predated GBS symptoms by nine days, in "first reported case" of such association); R. Bakshi and M. Graves, *Guillain-Barré Syndrome after Combined Tetanus-Diphtheria Toxoid Vaccination*, 147 J. Neurol. Scr. 201 (1997), filed as Ex. 42 (ECF No. 34-11)

("Bakshi & Graves") (discussing individual who satisfied the clinical, laboratory, and neurophysiological criteria of GBS, with onset four days after receipt of a tetanus-diphtheria toxoid vaccine). Bakshi & Graves was authored ten years after Newton & Janati—and by that date, the authors noted, only three case reports of GBS after receipt of tetanus toxoid-containing vaccines had been issued. Bakshi & Graves at 202.

Dr. Simpson also briefly discussed an even older case report. J. Pollard and G. Selby, *Relapsing Neuropathy due to Tetanus Toxoid*, 77 J. Neurol. Sci. 113 (1978), filed as 38 (ECF No. 34-7) ("Pollard & Selby"). Pollard & Selby involved a 42-year-old male who developed GBS after receipt of a tetanus-diphtheria vaccine on three difference occasions over a thirteen-year timeframe. Simpson First Rep. at 7. The patient's pathological and immunological studies demonstrated "similar pathogenetic mechanisms [that] are involved in the demyelination seen in [a] post-inoculation polyneuropathy as in the more usual post-infective variety." Thus, Pollard & Selby concluded that "there is little doubt that the [patient's] three clinical episodes of demyelinating neuropathy resulted from the administration of tetanus toxoid." Pollard & Selby at 117–18. (In fact, Pollard & Selby has been deemed to specifically involve chronic inflammatory demyelinating polyneuropathy ("CIDP"), rather than GBS, which is an acute and monophasic condition).[8]

Other support for a Tdap vaccine-GBS association was found, Dr. Simpson contended, in certain government-related publications. In 2011, for example, the Advisory Committee on Immunization Practice (the "ACIP") had deemed the development of GBS within six weeks following receipt of a tetanus toxoid-containing vaccine a precaution for subsequent vaccinations. Simpson First Rep. at 8; Center for Disease Control, *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MMWR 2011; 60 [No. RR-2]: 1-85 (January 28, 2011), filed as Ex. 46 (ECF No. 34-15) ("2011 ACIP Report"), at 63. In addition, Dr. Simpson maintained that the Institute of Medicine (the "IOM") had also embraced a possible association. Simpson First Report at 8, *citing* K. Kretsinger et al., *Preventing Tetanus, Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine,* MMWR 2006; 55 [No. RR-17]: 1–47 (December 15, 2006), filed as Ex. 47 (ECF No. 34-16) (the "2006 MMWR Report"), at 15 (noting that the IOM-embraced association was supported by a "single, well-documented case report"—Pollard & Selby (*see* 2006 MMWR Report at 15 n.147)).

Regarding the timeframe between Petitioner's likely onset and date of vaccination, Dr. Simpson maintained that Petitioner's medical records established that her new neurological symptoms (characterized by ascending numbness and paresthesias of the legs, lower extremity weakness and gait difficulty) had begun within five days of vaccination. Simpson First Rep. at 8.

[8] *See DeVaughn v. Sec'y of Health & Hum. Servs.*, No. 22-832V, 2025 WL 758128, at *21 n.21 (Fed. Cl. Spec. Mstr. Feb. 10, 2025).

Physical and diagnostic testing revealed objective neurological abnormalities, such as lower extremity weakness, hypesthesia, decreased reflexes, and elevated protein of 122 with low WBC count of 2. *Id.*; Ex. 10 at 16. The consensus among Petitioner's treating physicians was GBS. First Simpson Rep. at 8. Dr. Simpson opined that such a timeframe is consistent with a medically acceptable temporal relationship between Tdap and GBS. *Id.*

In concluding his first report, Dr. Simpson argued that "[t]here are no logical alternative potential causes of [Petitioner's] illness in this case other than [her] receipt of the Tdap vaccine." First Simpson Rep. at 8. He acknowledged that throughout 2019, Petitioner's medical records listed several diagnoses such as sinus infections, allergic rhinitis, bronchial spasm, cough, and a cat allergy. *Id.* However, Dr. Simpson maintained that Petitioner's treating physicians consistently documented "that [her] neurological symptoms of GBS began after the vaccination." *Id.* at 9. Therefore, and based upon Petitioner's clinical presentation and the overall sequence of events, Dr. Simpson opined that "it is more likely than not that the administration of the Tdap vaccination . . . caused her to develop GBS." *Id.*

Supplemental Report

Dr. Simpson's second written report briefly addressed a few comments found in the report of Respondent's expert, Dr. Matthew Brier. *See generally* Simpson Supp. Rep. at 1–3. He disagreed with Dr. Brier's assertion that Petitioner's GBS began one day post-vaccination, with complaints of back pain characterizing the onset of her disease. *Id.* at 1. Instead, Dr. Simpson maintained that Petitioner had a "well-documented long-standing history of low back pain with radicular symptoms in the lower extremities," and that, "[the] recurrence of severe back pain on [September 5, 2019] is completely consistent with [her] pre-existing history and [thus], i[t] is not indicative of the onset of GBS." *Id.*; *see* Ex. 10 at 25, 41; Ex. 11, 23, 41.

Dr. Simpson also reiterated his opinion that such early complaints were distinguishable from Petitioner's development of new symptoms five days post-vaccination (i.e., ascending numbness and paresthesias of the legs, lower extremity weakness, and gait difficulty). Simpson Supp. Rep. at 2. Relying on the medical records, Dr. Simpson noted multiple instances in which Petitioner's post-vaccination symptoms were distinct from her pre-vaccination exams—noting that "only mild distal [lower] [extremity] weakness was noted." *Id.*; *see also* Ex. 9 at 51; Ex. 14 at 33.

Second Supplemental Report

Dr. Simpson provided a second supplemental report in the matter, hoping to bulwark his proposed biological mechanism for how the tetanus vaccine can cause GBS in a susceptible individual. Simpson Second Supp. Rep. at 1. He noted additional medical literature reports that purport to demonstrate an association between the Tdap vaccine and GBS. *See generally* 2–4.

In particular, Dr. Simpson emphasized Petitioner's receipt of *two* Tdap vaccines within a span of four years as impacting her immune response, making it more robust and essentially triggering her GBS more quickly than usual. Simpson Second Supp. Rep. at 5. One item of literature had observed that approximately "99% of all subjects under the age of 60 demonstrated tetanus-specific antibody responses above the protective level of 0.01 IU/ml," and that "the overall half-life of tetanus-specific antibody was 14 years." *Id.* at 5 (citing E. Hammarlund et al., *Durability of Vaccine-Induced Immunity against Tetanus and Diphtheria Toxins: A Cross-Sectional Analysis*, 62 Clin Inf Dis 1111 (2016), filed as Ex. 62 (ECF No. 40-14)). It was therefore " reasonable to infer Petitioner's tetanus toxoid antibody titers *prior* to the 2019 vaccination would likely have been close to her titers following the 2015 tetanus vaccination, since the 4-year interval was *significantly less* than the 14-year half-life of tetanus vaccine antibodies." Simpson Second Supp. Rep. at 5 (emphasis in original). Since Petitioner had received these two boosters within a few years of each other, Dr. Simpson opined, it was likely that she "could have been more 'susceptible' to the second Tdap vaccination in 2019, triggering an aberrant immune response resulting in GBS." *Id.*

B. *Respondent's Expert — Matthew R. Brier, M.D., Ph.D.*

Dr. Brier, a neurologist, prepared a single written report in this matter. Report, dated Jan. 4, 2024, filed as Ex. A (ECF No. 35-1) ("Brier Rep.").

Dr. Brier attended the University of Texas at Dallas for his undergraduate degree, and Washington University, St. Louis for his medical degree and Ph.D. *See* Curriculum Vitae, filed Jan. 4, 2024 (ECF No. 35-2) ("Brier CV"); Brier Rep. at 1. He them completed an internship followed by his residency in Neurology at Barnes Jewish Hospital in St. Louis, Missouri. *Id.* Thereafter, Dr. Brier completed a fellowship in Multiple Sclerosis and Neuroimmunology at Washington University School of Medicine, where he is currently an Assistant Professor of Neurology and Radiology. Brier CV at 2; Brier Rep. at 1. He is board certified by the American Board of Psychiatry and Neurology. Brier CV at 3. Dr. Brier primarily treats demyelinating disorders of the central nervous system in his outpatient practice, but in an inpatient setting, he frequently treats individuals with GBS and its mimicking disorders. Brier Rep. at 1. He has published over forty peer-reviewed articles relating to the topics of neuroscience and neurology. *Id.*; Brier CV a 6–13.

Dr. Brier briefly discussed the pertinent medical history and facts herein before providing his overall opinion regarding diagnosis and causation. *See generally* Brier Rep. at 2–5. GBS, he explained, "is a monophasic, rapidly onsetting polyneuropathy." *Id.* at 6. Petitioner's medical history was characterized by her acute onset of pain, paresthesia and radicular pain, followed by distal to proximal weakness. *Id.* Moreover, she exhibited cranial nerve involvement, as well as autonomic involvement throughout the course of her illness, thus making the overall diagnosis of GBS most likely given her clinical presentation, in Dr. Brier's opinion. *Id.*

Dr. Brier, however, deemed Petitioner's onset to have been very close-in-time to her September 4, 2019 vaccination. First, he deemed significant her reports of back pain on September 5th, finding them to reflect "a clear deviation from [her] baseline," and thus likely evidence of her GBS onset. Brier Rep. at 7. Although the records did not explicitly note the difference in this pain from her documented pre-vaccination concerns, Dr. Brier nevertheless noted that Petitioner's September 5, 2019 pain was different enough to cause her to visit the emergency department as well as make several visits to her spine and pain management specialist—something she had not done previously with respect to her chronic back pain. *Id.* Thus, Dr. Brier opined that this worsening pain was "not simply an exacerbation of her chronic condition." *Id.*

Similarly, Dr. Brier noted the importance of Petitioner's complaints of double vision the day after vaccination, arguing that the improvement in Petitioner's double vision via retracting an eyelid or placing her chin down suggested that it "was caused by either a cranial nerve or central process." Brier Rep. at 7. Multiple forms of GBS are known to involve the cranial nerves, although in this case the lack of electrodiagnostic testing did not permit identification of the GBS subtype at issue. *Id.*; *see also* A. Gurwood & J. Drake, *Guillain-Barré Syndrome*, 77 Optometry – J. Am. Optometric Association 540 (2006), filed as Ex. C (ECF No. 35-3) ("Gurwood & Drake"). Nevertheless, "given [ ] the double vision onset around the time of the other GBS symptoms, that GBS can cause oculomotor symptoms leading to double vision, that the double vision resolved with treatment of GBS, and that no other etiologies were found for the double vision," Petitioner's double vision was more likely than not an aspect (and early harbinger) of her later-diagnosed GBS, along with her initial back pain complaints. Brier Rep. at 7; M. Dinkin, *Diagnostic Approach to Diplopia*, 20 Continuum: Lifelong Learning in Neurology 942 (2014), filed as Ex. D (ECF No. 35-4).

In fact, Dr. Brier noted, Petitioner had on September 5th complained of vision-related issues *predating* vaccination. This meant that her GBS onset may well have begun before September 4, 2019. Brier Rep. at 7. But even if Dr. Brier were to disregard Petitioner's visual disturbance, the presence of new, objective weakness by September 6, 2019—two days post-vaccination—did not align with the case reports cited by Petitioner. *Id.* at 7, 9 (referencing Bakshi & Graves (GBS onset four days after vaccination), Newton & Janati (GBS nine days post-vaccination), and Pollard & Selby (GBS recurrence no sooner than ten days, and after third dose of tetanus toxin). Otherwise, Dr. Brier deemed case reports to "only serve to establish that it is possible for one event (GBS) to follow another (vaccination), which is likely to occur by chance." Brier Rep. at 9.

Dr. Brier also questioned Petitioner's theory of causation, criticizing Dr. Simpson's claim that "[t]here is ample support in the medical literature for a connection between vaccination of various types and occurrence of demyelinating neuropathy." Brier Rep. at 8 (*citing* Simpson First Rep. at 7). He noted that much of the referenced literature was inapposite, since it pertained to the putative association between GBS and either the swine flu or the seasonal flu vaccines, and

therefore such evidence "does not [also] show that [the] Tdap [vaccine] causes GBS." Brier Rep. at 8; *see also* Safranek at 940 (discussing relationship between GBS and swine flu vaccine); J. Pritchard et al., *Risk of Relapse of Guillain-Barré Syndrome or Chronic Inflammatory Demyelinating Polyradiculoneuropathy following Immunisation*, 73 J. Neurol Neurosurg. Psychiatry 348–49 (2002), filed as Ex. 39 (ECF No. 34-8) ("Pritchard"). Pritchard was a questionnaire survey in which 3.5% of 311 GBS patients reported recurrence of symptoms after immunization (including tetanus-containing vaccines), but Pritchard's authors deemed the risk to be low and acknowledged that the study posed response bias methodologic limitations that reduced the predictive validity of its findings). Pritchard at 349.

Dr. Brier further maintained that certain IOM publications or reports were far less supportive of causation than assumed by Dr. Simpson. The alleged IOM acceptance of the causal relationship between tetanus-containing vaccines and GBS, for example, relied on the findings from Pollard & Selby—a case report later deemed not to have been substantiated by subsequent research. Brier Rep. at 9–10; 2006 MMWR Report at 15. Moreover, an updated version of the IOM report on adverse events associated with different vaccines had actually concluded that "[t]he evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis- containing vaccines and GBS." Brier Rep. at 10 (quoting *Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality* (K. Stratton et al., eds. 2012), filed as Ex. E (ECF No. 35-5) ("2012 IOM Report"), at 558).

In addition, several larger studies demonstrated a *decreased* risk of GBS following receipt of a Tdap vaccine, or failed to identify GBS as a safety signal following the vaccine's administration. Brier Rep. at 10–11; J. Tuttle et al., *The Risk of Guillain-Barré Syndrome after Tetanus-Toxoid-Containing Vaccines in Adults and Children in the United States*, 87 Am. J. Public Health 2045, 2048 (1997), filed as Ex. F (ECF No. 35-6) ("Tuttle") (concluding that "[i]f an association [between tetanus-toxoid-containing vaccines and GBS] exists, it must be extremely rate and not of public health significant.") P. Haber et al., *Safety Review of Tetanus Toxoid, Reduced Diphtheria Toxoid, Acellular Pertussis Vaccines (Tdap) in Adults Aged ≥ 65 Years, Vaccine Adverse Event Reporting System (VAERS), United States, September 2010 – December 2018*, 38 Vaccine 1476, 1480 (2020), filed as Ex. G (ECF No. 35-7) (identifying no new safety concerns over approximately a decade of recommended Tdap use for adults 65 years or older).

Dr. Brier concluded his report reiterating that Petitioner's symptoms had likely begun within no later than a day or two of vaccination—a timeframe wholly unsupported by any literature. Brier Rep. at 11. And the evidence offered to suggest a causal link between the Tdap vaccine and GBS, is "circumstantial and larger, more well-done studies fail to find an association," according to Dr. Brier. *Id.* Thus, it was more likely than not that Petitioner's development of GBS was not the result of her receipt of the Tdap vaccine. *Id.*

III. Procedural History

The claim was initiated in July 2022, and activated in September 2022 after completion of "pre-assignment review" (performed in all Vaccine Program cases to ensure sufficient records have been filed for case review). Petitioner's former counsel withdrew from the matter in July 2023 and a Consented Motion to Substitute Counsel was subsequently granted. *See* Clerk's Notice, filed July 25, 2023. Thereafter, the process of obtaining expert reports began, with the final report from Dr. Simpson filed in August 2024. The parties have now briefed their respective positions, and the matter is ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner maintains she has provided preponderant evidence of a credible medical theory causally connecting the Tdap vaccine to the development of GBS. Br. at 22. Dr. Simpson primarily replies upon the theory of molecular mimicry "as the most established mechanism," as it "suggests that epitopes of a virus or vaccine, results in development of immune antibodies and/or T cells that could cross-react with epitopes on myelin or axonal glycoproteins of nerves, leading to neuronal damage." *Id.*, *citing* Levin et al., *Neuronal Molecular Mimicry in Immune-Mediated Neurologic Disease*, 44 Annals of Neurology 87 (1998), filed as Ex. 36 (ECF No. 34-5). Moreover, his dependence upon the findings of a 1994 IOM report, which "discussed the evidence linking GBS to both the swine flu vaccine and rabies vaccine," is both relevant and reasonable herein. Br. at 26. Petitioner acknowledges that the 2012 IOM report concluded that the evidence was "inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccines and GBS;" but maintains that Dr. Simpson correctly interpreted its findings as an "independent conclusion." *Id.* at 30, *citing* 2012 IOM Report at 587. Additionally, Petitioner argues that Dr. Simpson—having coupled case reports[9] with other evidence, such as the 1994 IOM report—has represented by preponderance of evidence a sound and reliable medical theory causally connecting the vaccination and the injury. Br. at 36.

Next, Petitioner argues that she has presented preponderant evidence of a logical sequence of cause and effect showing that the Tdap vaccine caused her GBS. Br. at 42. To bulwark this assertion, Petitioner first notes the numerous treating physicians that causally connected her GBS to her September 4, 2019 vaccination. *Id.* at 43; *see also* Ex. 12 at 161, 168, 207; Ex. 28 at 79. She similarly maintains she suffered a robust systematic reaction to the vaccination, as evidenced by her documented treatment for myalgia pain, malaise, fatigue and dizziness within two days post-vaccination. Br. at 44. Accordingly, Petitioner contends that such symptomatology "exhibited a

[9] Petitioner is aware of the Program's view on case reports, however acknowledging that case reports are "[s]ituated on the lower end of the evidentiary scale, [and that] case reports rarely purport to establish causation definitively." Br. at 34.

clinically apparent immune response, emblematic of a severe reaction to the Tdap vaccine." *Id.* And having received a Tdap vaccination in 2015, Petitioner purports that she ultimately was not "immunologically naïve to the vaccine's components in 2019," but instead was "primed" by it to develop a strong secondary adaptive immune response, resulting in her development of GBS. *Id.* at 46.

As to the third *Althen* Prong, Petitioner maintains her onset of GBS occurred within a medically acceptable timeframe following her receipt of the Tdap vaccination. Br. at 47; *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Specifically, she points to record evidence documenting neurological symptoms beginning approximately five days post-vaccination, followed by progressive neurological signs of sensory and motor neuropathy, as falling within what is generally accepted in the medical literature regarding GBS post-vaccination. *Id.* at 48; *see also* Ex. 12 at 86 (discussing 9/11/2019 ER consultation with Dr. Talbert who noted petitioner has "increasing weakness in lower extremities [and] paresthesias to the right leg which is new since previous visit [on 9/6/2019]." Dr. Simpson further explains that Petitioner's clinical course aligns with an autoimmune cross-reaction with molecular mimicry via the adaptive immune response. Br. at 49. Petitioner disagrees with Dr. Brier's assertion that her back pain on September 5, 2019, represented "a clear deviation from [her] baseline [pain]," but instead maintains it reflected her pre-existing history of low back pain and "not indicative of the onset of [her] GBS." *Id.* at 50, 52.

In her reply, Petitioner maintains her ability to satisfy all three *Althen* prongs. Reply at 26. She contends that preponderant evidence exists to sufficiently demonstrate her development of GBS was not only caused by her receipt of the Tdap vaccine, but that Dr. Simpson put forth a sound and reliable biological mechanism—i.e., molecular mimicry—to causally link the vaccine and GBS. *Id.* Dr. Simpson's assertions, explains Petitioner, are "based upon the general understanding of GBS [and its] pathophysiology," emphasizing that "vaccines beyond the flu vaccine, including Tdap, can be implicated as triggers of GBS." *Id.* Petitioner further maintains the significance of Dr. Simpson's reliance on IOM reports finding that Tdap can cause GBS; studies suggesting an association between the natural tetanus infection and GBS; and public warnings regarding Tdap vaccines in individuals who have suffered GBS. Moreover, and in conjunction with treater statements causally connecting Petitioner's GBS with her receipt of the Tdap vaccination, as well as the (alleged) five-day onset of her neurologic symptoms, Petitioner contends she has satisfied her burden under *Althen* by offering preponderant evidence demonstrating that her GBS was caused by her September 4, 2019 vaccination. *Id.* at 27. Additionally, Petitioner disagrees with Respondent's assertion that her reported double vision and low back pain were evidence of an earlier onset. In so maintaining, Petitioner argues that Respondent "ignores" the medical records and facts of this case which, according to Petitioner, allow for the assumption that such symptoms could be associated with causes other than GBS (i.e., Petitioner's well-documented chronic sinusitis or chronic low back pain). *Id.*

Respondent

Respondent does not dispute Petitioner's diagnosis of GBS, but maintains that Petitioner has failed to satisfy her burden under *Althen*. Opp. at 13. Regarding prong one, Respondent argues that Petitioner has failed to present a reliable medical theory causally connecting the vaccination and her injury. *Id.* at 19. Epidemiology does not support Petitioner's claim. *Id.* Earlier IOM reports, he argues, "failed to consider, unlike the 2012 committee, that the [Pollard & Selby] case report does not involve GBS at all," but instead "is properly characterized as a case report of [CIDP]." *Id*. Moreover, earlier IOM reports are undermined by the conclusion of the 2012 IOM Report, with little to no new evidence developed since that might support the contention that tetanus-containing vaccines "can cause" GBS or CIDP, and the Program has repeatedly rejected reliance on Pollard & Selby. *Id*. at 20.

Respondent also maintains that the Government does not acknowledge a post-vaccination risk of GBS following receipt of a tetanus toxoid-containing vaccine, as suggested in *Mohamad v. Sec'y of Health & Hum. Servs.*, No. 16-1075V, 2022 WL 711604, at *18 (Fed. Cl. Spec. Mstr. Jan 27, 2022), *mot. for review den'd,* No. 16-1075V, 2024 WL 4993421 (Fed. Cl. Nov. 12, 2024), *appeal dismissed*, No. 2025-1370, 2025 WL 1341189 (Fed. Cir. May 8, 2025). Respondent in fact disagrees with the special master's interpretation and evaluation of the evidence submitted in *Mohamad*—noting specifically that the "IOM 'concluded that the evidence was inadequate to accept or reject a causal relation between receipt of diphtheria toxoid- and tetanus toxoid-containing vaccine' and GBS." Opp. at 22, *citing* Center for Disease Control & Prevention, *Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 67(2) CDC Morbidity & Mortality Wkly. Rep. 1 (Apr. 27, 2028), https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf (last visited June 13, 2025). Additionally epidemiological studies have consistently rejected a vaccine association. Opp. at 23; *see also* Tuttle at 1. And Dr. Simpson favors molecular mimicry as a possible mechanism mainly because it has scientific support in the context of GBS mediated by a wild infection—but otherwise the "non-specific invocation of molecular mimicry" has previously been rejected by this Court as "too generic to be a persuasive theory of causation in a specific case. Opp. at 27 *citing W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352 (Fed. Cir. 2013).

Similarly, Respondent maintains that Petitioner has failed to show a logical sequence of cause and effect between the Tdap vaccination and her GBS. Opp. at 30. According to Respondent, Petitioner presented no evidence demonstrating "that the manifestation of [her] GBS was somehow aberrant from a typical manifestation of GBS absent vaccination," and thus, her contention that the tetanus vaccination acts "as an inciting prodrome event" is not well supported. *Id.* at 31. Moreover, Respondent argues that Dr. Simpson's speculation—that Petitioner's prior receipt of a Tdap vaccine in 2015 could have caused her to be more "susceptible" to the second dose in 2019—

lacks "a hypothesis of *how* pre-existing antibodies might make [P]etitioner more susceptible to GBS." *Id.* Instead, Respondent maintains, "[i]f anything, the 2015 vaccination demonstrates that [P]etitioner has a history of tolerating the vaccine, making it less likely that her 2019 vaccination caused her GBS." *Id.* And while Petitioner relies on several treater statements as further evidence of causation, such statements do not satisfy her burden under *Althen* Prong Two, and that "[s]pecific attribution of GBS to vaccination is not truly discussed." *Id.* at 32. Therefore, the treater statements—which only were based on a temporal relationship, according to Respondent—are insufficient additional support for causation. Opp. at 32.

Lastly, Respondent argues that Petitioner has failed to establish a medically-appropriate temporal relationship between her receipt of the Tdap vaccine and the onset of her GBS—noting that her "GBS more likely than not predated vaccination and consisted of blurry vision/diplopia." *Id.* at 14. Based on the clinical presentation, Dr. Brier's opinion regarding Petitioner's visual symptomatology as the more likely onset of her GBS is well supported. *Id.* at 15. And the medical records do not demonstrate pansinusitis as the cause of Petitioner's visual disturbances which began acutely prior to her vaccination. *See* Ex. 12 at 370 (documenting improved visual impairments on discharge despite presence of pansinusitis on 9/11/2019 brain and orbit MRI). Petitioner continued to experience a progressive nature of pansinusitis on imaging, but her vision issues improved along with the improvement in her GBS symptomatology. Opp. at 14. Accordingly, Respondent maintains that the aligned improvement in visual and GBS symptoms ultimately supports the contention that her visual disturbances were more likely than not a manifestation of her GBS—thus, putting onset *prior* to vaccination. *Id.* at 14–15.

Respondent also discounts Petitioner's argument that her initial back pain symptoms were a continuation of her pre-vaccination status, rather than the start of her GBS. Although Petitioner had lumbar stenosis prior to her vaccination "secondary to [a] large synovial cyst and dynamic spondylolisthesis," she had experienced a near complete resolution of pain a little over a year prior to her receipt of the Tdap vaccine. *Id.* at 16 (*citing* Ex. 7 at 7). Moreover, the sudden/acute nature of Petitioner's GBS and vision symptoms suggest her post-vaccination symptoms were distinguishable from her otherwise well-documented and longstanding back issues. *Id.*

V. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; §

11(c)(1)(C)(ii)(I); *see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[10] There is no Table claim for GBS caused by a tetanus-containing vaccine.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface*, 165 F.3d at 1352–53); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or even a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are

[10] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their

suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his

contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*.,

No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See*, *e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not

been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Determination to Resolve Case without a Hearing*

I have opted to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means

of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

ANALYSIS

I. Overview of GBS and its Treatment in Prior Program Cases

GBS has been defined as an acute, monophasic peripheral neuropathy involving rapidly progressive and ascending weakness and paralysis, which is thought to have an autoimmune mechanism. P. Donofrio, *Guillain-Barré Syndrome,* 23 (5) Continuum J. 1295, 129 (2017), filed as Ex. 34 (ECF No. 34-3). In a subset of patients, GBS can result in cranial nerve palsies, including causing clinical symptoms like diplopia. Gurwood & Drake at 540–41 (documenting a case report of a patient experiencing intermittent diplopia after hospitalization for symptoms later diagnosed as GBS). Petitioner's GBS diagnosis is not contested by Respondent. Opp. at 13.

There is a large body of reasoned decisions[11] in which an association between the *flu vaccine* and peripheral neuropathies—most often GBS—has been established. Indeed, flu vaccine-caused GBS is a Table Claim. 42 C.F.R. § 100.3.14. This means the Government accepts that sufficiently-probative and reliable science on the topic exists to justify conceding causation, at least for Program purposes. *Haskins v. Secretary of Health & Hum. Servs.*, No. 18-1776V, WL 2020 1870279 (Fed. Cl. Spec. Mstr. Mar. 13, 2019). Even in cases where a Table element for such a claim cannot be met (for example, when onset is too short or too long to fit within the timeframe of 3–42 days set for the claim), any subsequent causation-in-fact analysis performed by the special masters does not usually require the claimant to offer proof in support of the "can cause" element; instead, it is reasonably assumed to be satisfied. *See Welch v. Sec'y of Health & Hum. Servs*. No. 18-494V, 2019 WL 349360 (Fed. Cl. Spec. Mstr. July 2, 2019).

Other vaccines have also been found causal of GBS, although there is disagreement among the special masters as to the preponderant strength of these proposed associations. *See, e.g.*, *Gross v. Sec'y of Health & Hum. Servs.*, No. 17-1075, 2022 WL 9669651, at *36–37 (Fed. Cl. Spec.

[11] Although prior decisions from different cases do not control the outcome herein, special masters may reasonably take into account, for guidance, the logic of such reasoned determinations. In fact, it is wise to do so, given how often similar causation theories or fact patterns arise in Vaccine Program cases.

Mstr. Sept. 22, 2022) (finding the pneumococcal vaccine caused GBS); *but see Trollinger v. Sec'y of Health & Hum. Servs.*, No. 16-473V, 2023 WL 2521912, at *30 (Fed. Cl. Spec. Mstr. Feb. 17, 2023), *mot. for review den'd*, 167 Fed. Cl. 127 (2023) (holding that the pneumococcal vaccine was not shown to cause GBS); *Bielak v. Sec'y of Health & Hum. Servs.*, No. 18-761V, 2022 WL 18058244, at *3 (Fed. Cl. Spec. Mstr. Dec. 9, 2022) (same). It thus cannot be said that the Program has developed a consistent view as to what the science preponderantly "says" about causation of GBS when the flu vaccine is not involved. Instead, it appears that the outcome in such cases is mostly a function of the evidence before the special master, with no clear trend one way or the other.

This is definitely true for claims that the Tdap vaccine can cause GBS. Several cases decided in the past ten years found *no causal association* between the two. *See, e.g.*, *Dennington v. Sec'y of Health & Hum. Servs.*, No. 18-1303V, 2023 WL 2965239 (Fed. Cl. Spec. Mstr. Apr. 17, 2023), *mot. for review den'd*, 167 Fed. Cl. 640 (2023), *appeal dismissed,* No. 2024-1214, 2024 WL 1255318 (Fed. Cir. Mar. 25, 2024); *Montgomery v. Sec'y of Health & Hum. Servs.*, No. 15-1037V, 2019 WL 2511352 (Fed. Cl. Spec. Mstr. May 21, 2019); *Tompkins v. Sec'y of Health & Hum. Servs.*, No. 10-261V, 2013 WL 3498652 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for review den'd*, 117 Fed. Cl. 713 (2014); *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2012), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013).

I have also decided a few cases in which I determined that the petitioner failed to establish a causal association between the Tdap vaccine and CIDP — a different injury from GBS, although also still a peripheral neuropathy (and Program claimants frequently rely on GBS-specific evidence in arguing that a vaccine can cause CIDP). *See, e.g.*, *DeVaughn v. Sec'y of Health & Hum. Servs.*, No. 22-832V, 2025 WL 758128 (Fed. Cl. Spec. Mstr. Feb. 10, 2025); *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, 2022 WL 4869354 (Fed. Cl. Spec. Mstr. Aug. 31, 2022), *mot. for review den'd*, No. 16-1592V, 2023 WL 4117370 (Fed. Cl. May 18, 2023), *aff'd*, No. 2023-1816, 2024 WL 2873301 (Fed. Cir. June 7, 2024); *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 18-1012V, 2022 WL 1013264, at *1 (Fed. Cl. Spec. Mstr. Mar. 11, 2022).

Prior Tdap-GBS cases have often involved causation theories comparable to what is offered in this case. In *Isaac*, for example, the petitioner proposed molecular mimicry as the causal mechanism. *Issac*, 2012 WL 3609993, at *6. But the special master determined that the petitioner's expert had over-relied on a single case report[12] to prove causation, without adequately substantiating the mechanism. *Id.* at *20–21. This determination was affirmed on appeal at the Court of Federal Claims and Federal Circuit. In *Tompkins*, the special master denied entitlement in a case alleging that a number of vaccines received at the same time (including Tdap) caused a

[12] The case report mentioned in *Issac* was Pollard & Selby.

petitioner's GBS, but the causal theory put forward attempted to assert that the vaccines could also individually trigger the disease. *Tompkins*, 2013 WL 3498652, at *15. The petitioner's expert, however, relied heavily on VAERS passive surveillance data,[13] and otherwise invoked a number of theories (molecular mimicry, or endotoxin in tetanus-containing vaccines) that were only cursorily substantiated. *Id.* at *19–23.

I have in some of my relevant prior decisions also observed issues with the reliability of the findings proposed by Pollard & Selby, one of the most on-point case reports offered herein. As I noted in *DeVaughn*, 2025 WL 758128, at *20:

> Pollard & Selby deserves even less weight. In this quite-old case study, a patient's acute idiopathic polyneuropathy relapsed on three occasions, each purportedly following a tetanus vaccination. Pollard & Selby at 113. But its authors did not consider alternative explanations for these spontaneous relapses, nor did they provide evidence beyond a temporal association. . . The authors also failed to explain *how*, or by *what* mechanism, a tetanus toxoid antigen could stimulate CIDP, even if some association had been demonstrated in this single patient. . . . And Pollard & Selby's findings remain uncorroborated, over 45 years later, by subsequent (and more reliable) studies that might confirm what it suggests is possible. It cannot stand as persuasive evidence for causation. *Tompkins*, 2013 WL 3498652, at *26 (observing that an absence of evidence in the years after publication of a case report or series corroborating its suggestions about a vaccine-injury association undermines the initial report's causal significance, and suggests its findings reflect only chance).

Admittedly, other special masters have deemed causation demonstrated in a Tdap vaccine-GBS case. *See Harris v. Sec'y of Health & Hum. Servs.,* No. 18-944V, 2023 WL 2583393 (Fed. Cl. Spec. Mstr. Feb. 21, 2023); *Mohamad*, 2022 WL 711604, at *18. In *Mohamad*, a special master ruled in petitioner's favor in a Tdap-GBS case, but almost wholly based on the determination that the Government had effectively conceded the first *Althen* Prong. In particular, the special master observed that (a) in 2011, the IOM had noted a precaution to receipt of the Tdap vaccine in the

[13] The Vaccine Adverse Event Reporting System ("VAERS") is a national warning system designed to detect safety problems in U.S.-licensed vaccines. *See About VAERS*, VAERS, https://vaers hhs.gov/about html (last visited June 13, 2025). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals. But it has been observed in the Program that VAERS data is not particularly probative of causation unless supplemented with other reliable evidence—since a VAERS report only establishes a temporal, post-vaccination occurrence. *See also Vig v. Sec'y of Health & Human Servs.*, No. 01–198V, 2013 WL 6596683, at *17 (Fed. Cl. Spec. Mstr. Nov. 14, 2013) ("VAERS is a stocked pond, containing only reports of adverse events after vaccinations but no data about the number of vaccines administered or the occurrence of the same adverse event in individuals who have not been vaccinated").

future if an immunized individual had developed GBS within six weeks of a prior dose,[14] and (b) this precaution note (along with an acknowledgment of the possibility of encephalopathy in a seven-day timeframe) had been maintained in subsequent ACIP reports, despite interim findings that the tetanus-GBS link was not as well-established as previously thought. *Mohamad,* 2022 WL 711604, at *13–15. From this (and also on the basis of credibility determinations specific to the experts who had testified in that case), the special master concluded that the first *Althen* prong was satisfied. *Id.* at *7, 15–18.

I am unpersuaded by the reasoning employed in such cases (independent of the fact that they do not bind this determination), since they give too much weight to Government policy-related pronouncements, over actual scientific and medical evidence of putative causation. But these cases, along with those going the other way, all establish that claims relying on the Tdap vaccine's association with GBS are not categorically ruled out—even if the theory they espouse has also not been fully accepted.

II. Petitioner Has not Carried Her Burden of Proof

It is well established that claimants must meet all three *Althen* prongs—and that a special master may therefore limit analysis of the strength of a petitioner's causation showing to only the prong(s) deemed unsatisfied. *Dobrydnev v. Sec'y of Health & Hum. Servs*., 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). This claim founders on Petitioner's inability to demonstrate preponderantly the third *Althen* prong—that her GBS onset began in a medically-acceptable timeframe, measured from the September 4, 2019 date of vaccination. For even if I could find that the Tdap vaccine "can cause" GBS—and as the discussion above suggests, I strongly lean against such a conclusion—Petitioner's GBS began too soon after vaccination to link the two events causally.

A temporal association alone between a vaccination and subsequent disease "does not suffice to show a causal link" between the two. *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Rather, the third *Althen* prong requires petitioners to establish a "*proximate* temporal relationship." *Althen*, 418 F.3d at 1281 (emphasis added). To do so, the claimant must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *De Bazan*, 539 F.3d at 1352. The explanation for what is a "medically acceptable timeframe" must align with the theory of how the relevant vaccine can cause an injury. *Id*.

In the Vaccine Program, onset of an alleged vaccine injury is marked by the "first symptom or manifestation of onset." See Section 16(a)(2). As the Federal Circuit stated in *Markovich v.*

[14] Also of note is the fact that this specified circumstance (advising against receipt of the Tdap vaccine if an individual previously developed GBS after a prior Tdap dose) is facially distinguishable from the claim that a single dose can cause GBS for the first time. And it gives weight to the development of GBS after a second dose, while ignoring the implications of receipt of prior doses without also development of GBS.

Sec'y of Health & Hum. Servs., 477 F.3d 1353, 1357 (Fed. Cir. 2007), there is a difference between a "symptom" and "manifestation of onset"—but because of the Act's use of the disjunctive "or," either can constitute the start of a disease process (even though a symptom could be nonspecific, or hard to link to what was later viewed as a full disease). *Markovich*, 477 F.3d at 1357–59.

By contrast, the date of diagnosis (which may in turn result from the accumulation of clinical and testing evidence over time) does not mark the onset of an alleged vaccine injury. *Carson v. Sec'y of Health & Hum. Servs*., 727 F.3d 1365, 1369 (Fed. Cir. 2013). Onset may occur even before the ill individual understands a presenting symptom to be concerning. *See Markovich*, 477 F.3d at 1357 ("[a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury") (emphasis added).

The medical record in this case best supports the conclusion that Petitioner's onset most likely began no *later* than September 5, 2019—one day post-vaccination. She first sought medical care two days post-vaccination, complaining of symptoms that could be deemed in isolation to be nonspecific—but which (in hindsight) appear likely associated with her later diagnosis. Ex. 12 at 10–11. She later expressly told treaters she had experienced sudden, intense back pain on September 5th, plus leg weakness—and Dr. Brier persuasively interpreted that to be GBS-related. Ex. 28 at 73–74; Brier Rep. at 3, 6–7. She also reported the same onset date for pain at a pain management treatment visit around this time. Ex. 10 at 16. And Petitioner consistently reported to treaters later on that her issues began around the time she was vaccinated. *See, e.g.*, Ex. 29 at 6 (September 13, 2019 EMS treatment record); Ex. 12 at 137 (mid-September hospitalization record). While Petitioner has offered witness statements attempting to challenge this temporal sequence (*see, e.g.*, Ex. 63 (Supplemental Affidavit, dated Aug. 9, 2024 (ECF No. 40-15)), the records themselves are strong and reliable proof that deserve greater weight in my analysis.

Further, Respondent has established that complaints of back pain (in conjunction with the other symptoms complained of at the same time) would likely reflect the start of GBS. *See* Opp. at 16–17. This conclusion has independent scientific/medical support. *See* B. Wakerley & N. Yuki, *Mimics and Chameleons in Guillain–Barré and Miller Fisher Syndromes,* 15 Pract. Neurol. 90–99 (2015), filed as Ex. H (ECF No. 44-1) at 91 (stating that "[i]n our experience, many patients with GBS also report back pain, probably relating to inflammation of nerve roots"); *see also Larson v. Sec'y of Health & Hum. Servs.*, No. 16-633V, 2023 WL 3765631, at *11, *14 (Fed. Cl. Spec. Mstr. June 1, 2023) (noting the agreement among experts that lower back pain is common in GBS and often is a presenting feature of it). Whether or not the Tdap vaccine *could have caused* these symptoms, such reporting to contemporaneous treaters of what Petitioner deemed an urgent medical concern corroborates a close-in-time onset.

It arguably could be concluded from this record that Petitioner's onset *predated* vaccination (in which case there would be no possibility of finding the Tdap vaccine caused her GBS).[15] If Petitioner's diplopia (for which she saw treatment the day after vaccination) was, as Dr. Brier surmised, associated with her GBS, then since she noted on September 5th it had begun two days earlier, her GBS had actually already manifested before vaccination. Ex. 15 at 5. But more often than not, such cranial-located symptoms would follow temporally *after* GBS's more classic presenting symptoms of ascending leg and arm weakness,[16] and Petitioner has offered some credible explanation for this initial treatment visit, arguing that it was associated with chronic sinusitis. Ex. 63 at ¶¶ 2–3. In any event, there is *more* record evidence suggesting that the concerns that lead Petitioner to seek treatment in mid-September began the day after vaccination—and I base this kind of fact finding on a balancing of the totality of the evidence.

Dr. Simpson was unsuccessful in his efforts to construe the record to support an onset of five or more days post-vaccination. His analysis gives too much weight to when treaters were able to *diagnose* Petitioner with GBS—even though, as noted above, onset turns on the *first* manifestation of a disease, regardless of whether diagnosis was then possible. First Simpson Rep. at 8. At the same time, Dr. Simpson unpersuasively dismisses Petitioner's September 5th complaints of back pain, attributing them to her prior chronic concerns—even though the medical records do not establish any such complaints in the earlier months of 2019 (and in fact at best show the last back-related treatment occurred in the winter of 2018. Ex. 10 at 25, 29).[17] While it is true that Petitioner had a "well-documented" history of back pain (Simpson Supp. Rep. at 1), her prior issues can be distinguished from what she experienced in September 2019—especially since those back pain complaints not only were reported in a context of other symptoms, but also since she went on to be properly diagnosed with GBS within days (thus corroborating an association). The totality of evidence supports the conclusion that her September 5, 2019 symptoms were likely GBS-associated.

Such a short, one-day onset timeframe is not consistent with Petitioner's causation theory. Petitioner proposes molecular mimicry as "the most established mechanism" for explaining how the Tdap vaccine could cause GBS. Br. at 24–25. Molecular mimicry (in which the immune system cross-reacts against self-tissues, due to similarity between amino acid sequences in a foreign antigen and self-structures) involves the adaptive immune system—the secondary immune arm,

[15] Of course, claimants can assert that a pre-vaccination injury was *exacerbated* by a vaccine—but this does not characterize the cause of action Petitioner has advanced.

[16] This is in fact what appears to have occurred in the Gurwood & Drake case report offered by Dr. Brier. That patient was hospitalized a week after "an episode of progressive leg weakness, generalized ataxia," and other symptoms—with ocular-associated complaints manifesting later. Gurwood & Drake at 540.

[17] In fact, as Respondent observes, there is evidence suggesting that Petitioner's earlier pain had resolved well before her September 2019 vaccination. Opp. at 16, *citing* Ex. 7 at 21. And she did not subsequently complain of it again, prior to September 5th. Ex. 11 at 57–59; Ex. 8 at 7–8.

which does not immediately respond to a vaccine upon administration.[18] *Dennington*, 2023 WL 2965239, at *20. Rather, this process takes more than a day to result in the production of antibodies capable of a cross-reactive, autoimmune attack. Authority filed in this case (including the 2012 IOM Report) is consistent with a longer timeframe for the adaptive response, taking no less than four days before clinical manifestation caused by antibody production capable of subsequent autoimmune attack. 2012 IOM Rep. at 57–58; *see also Brancheau v. Sec'y of Health & Hum. Servs.*, No. 21-1209V, 2024 WL 1619606, at *23–24 (Fed. Cl. Spec. Mstr. Mar. 21, 2024).

Indeed, even in the context of *the Table claim for GBS after receipt of the flu vaccine* (the elements of which are frequently invoked by claimants even when seeking to prove a different vaccine could also cause GBS—*and which are referenced here as well*),[19] clinical onset within three days of vaccination is *almost always* deemed too fast to be medically acceptable, unless there are demonstrated unique circumstances relating to the claimant's own medical history not shown present herein. A finding of GBS onset occurring within 24 hours of receipt of the *flu vaccine* would likely thwart even an off-Table version of such a claim. *Rowan v. Sec'y of Health & Human Servs*., No. 17-760V, 2020 WL 2954954 (Fed. Cl. Spec. Mstr. April 28, 2020) (finding that GBS is known to be mediated by autoantibodies produced via the adaptive immune system, and this process, if vaccine-induced, likely takes longer than three days to result in symptoms). It is thus very difficult to conceive of how the acceptable timeframe could be shorter for the Tdap vaccine—whose analogous wild viral components are *far less associated* with GBS than a wild flu virus infection.

Dr. Simpson attempted to rebut the foregoing by arguing that Petitioner's prior receipt of Tdap boosters meant she would likely experience a much faster onset as a result of prior immune "experience" with the vaccine. *See, e.g.*, Second Supp. Simpson Rep. at 5. But this contention was not sufficiently substantiated. At most, he offered some reliable evidence about *how long* the immune system maintains immunity to Tdap vaccine components. But this does not mean the response to subsequent exposures would likely result in an antibody-driven disease response beginning *the day after* vaccination. It does not lead to the conclusion that each subsequent receipt of a Tdap booster produces an ever-faster adaptive response—or one that would necessarily be pathologic. And the four-year gap between when Petitioner received the two Tdap doses (2015 to 2019) is hardly a "close proximity," as Dr. Simpson proposes. *Id.*

I also echo the point made by Dr. Brier about the case reports filed in this case, and what they suggest about a reasonable timeframe for Tdap vaccine-triggered GBS. Case reports are well

[18] Even if Petitioner herein were to contend that GBS is the product of some other kind of mechanism *not* involving the adaptive arm of the immune response, such a contention would swim against the stream of all Program cases involving GBS—which deem it to most likely be mediated *initially* by an antibody-driven cross-reactive attack against self—hence, a process involving the adaptive response to vaccination. *See A.T. v. Sec'y of Health & Hum. Servs.*, No. 20-1716V, 2024 WL 2764822, at *11 (Fed. Cl. Spec. Mstr. Apr. 24, 2024).

[19] *See, e.g.*, Simpson Supp. Rep. at 2 (referencing Table onset period for claim of GBS caused by flu vaccine); Br. at 25–26.

understood in the Vaccine Program to constitute extremely weak causation evidence. *Knorr v. Sec'y of Health & Hum. Servs.*, No. 15-1169V, 2018 WL 6991548, at *30 (Fed. Cl. Spec. Mstr. Dec. 7, 2018) (citations omitted). And I have already noted reasons to give certain of them filed in support of Petitioner's claim—Pollard & Selby in particular—very little weight, even if they also involve tetanus-containing vaccines. But setting aside such reasonable qualms, the case reports offered *in this case* of GBS occurring after the administration of the Tdap vaccine involved *longer* post-vaccination timeframes than what the record supports likely occurred here. *See, e.g.*, Bakshi & Graves (four days), Newton & Janati (nine days), and Pollard & Selby (ten days at the earliest). This is consistent with what is known about GBS's pathogenesis—but not consistent with Petitioner's medical history.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[20]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[20] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.